1. (Amended) A method for the management of incontinence in a patient, wherein the method comprises admitting orally into the patient a dosage form comprising 240 ng to 650 mg of a member selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt, that releases the member at a controlled and sustained, substantially zero order rate of 0.05 mg per hour up to 0.850 mg per hour for about 24 hours.

32. (Amended) A pharmaceutical dosage form comprising 240 ng to 650 mg of a member selected from the group consisting of oxybutynin and its pharmaceutically acceptable salts, the dosage form being adapted to release the member at a controlled and sustained, substantially zero order release rate for about 24 hours.

REMARKS

This amendment is filed in response to the Office Action dated March 13, 2002.

Claims 1, 32 and 33 are pending in the application. Claim 33 is cancelled herein.

Claims 1, 32 and 33 are rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification does not reasonably provide enablement for oxybutynin and its pharmaceutically acceptable salt as claimed by Applicants.

Claims 1, 32 and 33 are further rejected under the judicially created doctrine of double patenting over all claims of U.S. Patent Nos. 5,674,895; 5,840,754; 5,912,268; and 6,262,115.

Claim Rejections – 35 U.S.C. § 112, first paragraph

Claims1, 32 and 33 are rejected under 35 U.S.C. §112, first paragraph, because the specification does not reasonably provide enablement for oxybutynin and its pharmaceutically acceptable salt. In particular, the Examiner asserts that the specification does not enable any person skilled in the art to make the invention commensurate in scope with these claims. The Examiner states that Applicants disclose use of 240 ng to 650 mg of oxybutynin and its pharmaceutically acceptable salt released over a 24-hour period at a controlled and sustained, zero order rate of release.

Applicants amend independent Claims 1 and 32 to further particularize the invention as delivering oxybutynin at a controlled and sustained, substantially zero order rate of release. Support for this amendment can be found in dependant Claim 33, which is canceled herein and incorporated into Claims 1 and 32; page 2, lines 30-32; page 4, lines 5-7; and page 14, lines 2-4; for example.

Accordingly, Applicants respectfully request that the Examiner's rejection be withdrawn and the application proceed to issuance.

Double Patenting

Claims 1, 32 and 33 are rejected under the judicially created doctrine of obviousness-type double patenting over all claims of U.S. Patent Nos. 5,674,895; 5,840,754; 5,912,268; and 6,262,115.

Applicants file a terminal disclaimer herewith over U.S. Pat. Nos. 5,674,895; 5,840,754; 5,912,268; and 6,262,115 in anticipation of allowance of the instant claims.

Reconsideration of the application is respectfully requested.

Accordingly, Applicants believe that the present application is in a condition for allowance. Should any further changes be deemed necessary, the Examiner is invited to contact the undersigned attorney at the telephone number provided.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

The Commissioner is hereby authorized to charge any additional fees associated with this paper or during the pendency of this application, or credit any overpayment, to Deposit Account No. 01-1173.

ALZA CORPORATION

Respectfully submitted,

Dated: June 13, 2002

ALZA Corporation
1900 Charleston Road Bldg. M10-3
Mountain View, CA 94043-7210
650-564-5171

Robert R. Neller
Registration No. 46,950
Attorney for the Applicants

Version with markings to show changes made

In the Claims:

1. (Amended) A method for the management of incontinence in a patient, wherein the method comprises admitting orally into the patient a dosage form comprising 240 ng to 650 mg of a member selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt, that releases the member at a controlled and sustained, substantially zero order rate of 0.05 mg per hour up to 0.850 mg per hour for about 24 hours.

32. (Amended) A pharmaceutical dosage form comprising 240 ng to 650 mg of a member selected from the group consisting of oxybutynin and its pharmaceutically acceptable salts, the dosage form being adapted to release the member at a controlled and sustained, substantially zero order release rate for about 24 hours.